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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,067	03/31/2004	Sin Chung	206,488	8461

7590 05/23/2006

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/816,067	CHUNG, SIN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Zachariah Lucas	1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 6-13 is/are pending in the application.
- 4a) Of the above claim(s) 6-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 1-3 and 6-13 are pending in the application.
2. In the prior action, mailed on February 7, 2006, claims 1-13 were pending in the application, with claims 1-5 under consideration and rejected, and claims 6-13 withdrawn as being drawn to a nonelected inventions. In the Response of May 3, 2006, the Applicant cancelled claims 4 and 5, and amended claims 1-3.
3. Claims 1-3 are under consideration.

#### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. **(Prior Rejection- Withdrawn)** Claims 4 and 5 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the cancellation of these claims, the rejection is withdrawn.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. **(Prior Rejection- Maintained)** Claims 1-5 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. These claims were rejected

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because the application is not enabling for the use of any composition comprising any euglobulin. Claims 1-3 have been amended to indicate the intended use of the composition to treat canine distemper. Claims 4 and 5 have been cancelled. The rejection is therefore withdrawn from cancelled claims 4 and 5.

The Applicant traverses the rejection with respect to claims 1-3 on the basis that those of ordinary skill in the veterinary arts would have immediately known that the euglobulin obtained from any animal would be useful in the claimed invention. This argument is not found persuasive because there is no indication that the common immunostimulatory properties of euglobulins in general is source of the ability of the *M. albicans* composition to treat canine distemper, particularly in view of the fact that canine distemper is caused not by the *M. albicans* fungus, but by an unrelated virus. See e.g., App., page 1. As there is no indication as to what properties of the *M. albicans*/euglobulin combination results in the ability of the composition to treat canine distemper, those in the art would not have expected, without more, that any euglobulin could be combined with the fungal solution to achieve the same results (for the reasons described in the prior action). The rejection is therefore maintained against pending claims 1-3.

8. **(Prior Rejection- Maintained)** Claims 4 and 5 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the application has not provided sufficient descriptive support for a genus of compositions comprising any euglobulin (i.e. euglobulin from any source) that are useful for the treatment of the indicated disorders, including canine distemper. While claims 4 and 5 have been cancelled, the limitation of claim 4 has now been incorporated into claims 1-3.

The Applicant traverses the rejection on the basis that claims 4 and 5 have been cancelled. However, in view of the amendment of claim 1 (and thus of dependent claims 2 and 3) the rejection is maintained for the reasons of record against amended claims 1-3.

9. **(Prior Rejection- Withdrawn)** Claim 5 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the application has not demonstrated that the claimed composition would be useful for the treatment of all neurological disorders falling within the indicated group. In view of the cancellation of claim 5, the rejection is withdrawn.

10. **(Prior Rejection- Withdrawn)** Claim 5 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement with respect to pharmaceutical compositions that are effective for the treatment of a genus of conditions comprising any neurological condition. In view of the cancellation of the claim, the rejection is withdrawn.

### ***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. **(Prior Rejection- Maintained)** Claims 1, 3, 4, and 5 were rejected under 35 U.S.C. 102(b) as being anticipated by Lott et al. (U.S. 5,688,644). Claims 4 and 5 have been cancelled from the application. The rejection is therefore withdrawn from these claims. Claims 1 and 3 have been amended to note that the composition is for treating canine distemper.

The Applicant traverses the rejection on the basis that the claims have been amended to require that the composition is for the treatment of canine distemper, and that the reference does not teach such a use. However, the present claims are directed to compositions of use, not to methods of treatment. Thus, the reference to the treatment of canine distemper represents only an intended use of the claimed composition.

A recitation of the intended use of the claimed invention **must result in a structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See e.g., MPEP §§ 2111.02 II, and 2114. In the present case, the claims read on any composition comprising a disrupted cell suspension of *M. albicans* and euglobulin. Such a composition is described by the reference. The Applicant has provided no structural means for differentiating the composition of the reference from that of the claims, and has not established that the added functional language results in the exclusion of the reference as prior art (e.g., by demonstrating that the composition of the reference would not be capable of performing the intended use). The rejection is therefore maintained.

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13. **(Prior Rejection- Maintained)** Claims 1, 3, 4, and 5 were rejected under 35

U.S.C. 102(b) as being anticipated by Bergeron et al. (U.S. 2003/0049636): The claims have been described above. The Applicant traverses the rejection on the same grounds as were asserted with respect to the Lott reference above. The rejection is maintained over claims 1 and 3 for the same reasons as described with respect to Lott above.

14. **(Prior Rejection- Maintained)** Claims 1, 3, 4, and 5 were rejected under 35

U.S.C. 102(e) as being anticipated by Picard et al. (U.S. 2004/0076990). The claims have been described above. The Applicant traverses the rejection on the same grounds as were asserted with respect to the Lott reference above. The rejection is maintained over claims 1 and 3 for the same reasons as described with respect to Lott above.

### ***Conclusion***

15. No claims are allowed.

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

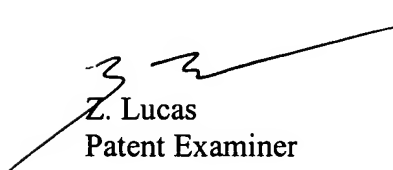
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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

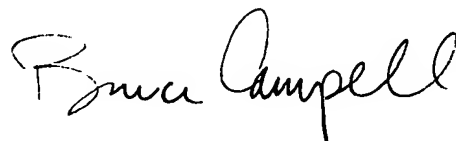
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas  
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